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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/852,872 05/10/01 LAPPE

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023589 MMC2/1102
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EXAMINER

DUNN, D

ART UNIT

PAPER NUMBER

2882

DATE MAILED:

11/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| | | | |
|------------------------------|--------------------------------------|------------------------------|---|
| Office Action Summary | Application No. 09/852,872 | Applicant(s) Lappe |  |
| | Examiner Drew A. Dunn | Art Unit 2882 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on _____

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-21 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) 1-14 is/are allowed.

6) Claim(s) 15-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 10 May 2001 is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

| | |
|--|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ | 20) <input type="checkbox"/> Other: _____ |



UNITED STATES DEPARTMENT OF COMMERCE
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Paper No. 2

Application Number: 09/852,872

Filing Date: 05/10/01

Applicant(s): Lappe

DETAILED ACTION

Reissue Applications

This reissue application was filed without the required offer to surrender the original patent or, if the original is lost or inaccessible, an affidavit or declaration to that effect. The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 C.F.R. 1.178.

Oath and Declaration

The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 C.F.R. 1.175(a)(1) and MPEP § 1414.

Applicant needs to “specifically” state at least one error, not generally state that they (the patentees) have claimed less than they had a right to claim.

Claims 1-21 are rejected as being based upon a defective reissue declaration under 35 U.S.C. 251 as set forth above. See 37 C.F.R. 1.175.

Proposed Preliminary Amendments

The amendment for updating the continuity of the parent application is questioned since there is no statement as to error or affidavit or other supporting evidence or argument that such a correction from continuation to CIP is required.

Drawings

The drawings are further objected to under 37 C.F.R. 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "method steps of claims 20 and 21" must be shown or the feature(s) cancelled from the claim(s). No new matter should be entered.

Recapture

Claims 15 and 17-21 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within

the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

Specifically, applicant included the subject matter that “said indicia at least one analysis element, at least one fixed element and at least one blank region therebetween” wherein the addition of the “blank region therebetween” was added to the independent claims 1 and 7 so as to make said claims novel and non-obvious. This amendment was done on 1/4/99 in the parent case and argued, in the accompanying arguments, as the reason for novelty. Lastly, such arguments and amendment were deemed persuasive and as such, the parent applicant was passed to issue.

Claim Rejections - 35 U.S.C. § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear as to how applicant can have a indicia that is not human readable with the system that is disclosed. Specifically, if it was applicant's intention to imply that a indicia such as barcode is not human readable because of the changes in lines and spacings being to insignificant for the human eye to perceive, then applicant must properly disclose and discuss such issues. As it stands, humans can read a barcode and though it might be difficult to understand, it is probably no more difficult nor different than having a 10 digit prime number that

is indicative of something else. Therefore, applicant needs to properly define and claim their invention while **not adding new matter to the claims or specification.**

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochstrasser (U.S. Pat. Nos. 4,042,329 and 4,059,407).

Hochstrasser discloses a method and device for detecting cholesterol which includes an analysis means defined by reagent zones (11, 12, 13 and 14) which are impregnated upon a test surface (18). Specifically, Hochstrasser discloses the determination of chemical substances in biological fluid. It would not have been a stretch for one of ordinary skill in the art to recognize the teachings of Hochstrasser and apply it to drug testing in urine (by changing the chemicals on the assay that react) since this would constitute the determination of a chemical substance (drugs) in a biological fluid (urine). Also, these reagent zones detect and optically signal, by changing color, the presence and concentration (i.e. a desired state) of a specific chemical. Further, Hochstrasser discloses that a reading device, for reading the analysis means, can be an optical scanning device (see column 14 lines 32-41). Hochstrasser also discloses a machine readable indicia (the numerals 1,2, 3 and 4) which act as specific encoded data, and though Hochstrasser

fails to disclose a bar code indicia, choosing one form of indicia for another (i.e. a bar code for alphanumeric) would have been obvious to an artisan due to the interchangability of indicia and is not deemed novel.

It is well recognized in the art of data processing that the choice between one form of data identifying and scanable indicia and another, including indicia formed by individual components or a series thereof, are obvious interchangeable choices of design and therefore, without overcoming a stated problem, the choice of one form of indicia versus another is not deemed novel. Further, having the indicia react to multiple reagents or having a "control" or test portion to maintain quality control would not only have been obvious to an artisan, but is generally standard procedure when running test sample analysis.

Applicants claims are for drug screening (i.e. a chemical in a biological fluid) which is addressed *supra*. However, though Hochstrasser fails to teach the "barcode" arrangement, the teachings of generic numbers and geometric shapes are as indistinguishable as to providing information as a barcode since these shapes can having any meaning desired. Applicant's claims include the limitations of the "assaying indicia being machine readable and not human readable." As discussed above, and in light of applicant's disclosure, the geometric shapes are a human readable as a 10 digit prime number as pertains to one understanding the nature of the information provided by the changing indicia and as such, this feature is deemed obvious.

Lastly, having quality control information to provide that the assay is properly functioning is well known and would have been obvious since the threat and problems associated with an inaccurate reading are very dangerous, costly and well understood in the art.

As pertains to claims 20 and 21, the system methods are suggested, as stated *supra*, by Hochstrasser's method and the well known process for drug testing. Also, Hochstrasser fails to teach the transmission of the data to a remote location, such automated transmitting systems are known and since drug tests are manually transmitted, the choice of automating such a system would have been within the ordinary skill in the art. *In re Venner*, 120 USPQ 192.

Allowable Subject Matter

Claims 1-14 are allowable over the prior art of record.

Claim 16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: with regards to claims 1-10, though the prior art discloses assay arrangements for determining the presence of a chemical in biological fluid by way of signaling through an indicia or machine readable code, said assay being on a substrate that is capable of receiving said biological fluid, it fails to teach or suggest that the indicia includes at least one analysis element, at least one fixed element and at least one blank region therebetween

With regards to claims 11-13, the prior art also fails to teach or suggest the machine readable assaying system wherein the card has an initial machine readable encoded value, the assaying indicia capable of detecting and optically signaling the presence of a desired state,

wherein one the desired state is detected, the assaying indicia forms a second machine readable encoded value.

With regards to claim 16, this subject matter is allowable for the reasons set forth supra regarding claims 1-10.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Drew A. Dunn** whose telephone number is (703) 305-0024. The examiner can normally be reached between the hours of 8:00 AM to 3:00 PM Monday thru Thursday and every other Friday (second Friday of the bi-week).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert H. Kim, can be reached on (703) 305-3492. The fax phone number for this Group is (703) 308-7722 or (703)308-7724.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [drew.dunn@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0956.



Drew A. Dunn
Primary Examiner
Art Unit 2882
19 October 2001